

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

03-0157-P-0096

DEAN LANGFORD and  
NANCY LANGFORD,  
husband and wife,

Case No.: 03-12245-RCL

Plaintiffs,

v.

ZIMMER, INC. and  
ZIMMER HOLDINGS, INC.,

Defendants.

JURY TRIAL DEMANDED

**ANSWER OF ZIMMER HOLDINGS, INC.**  
**[SUBJECT TO MOTION TO STRIKE]**

For its First Amended Answer to Plaintiffs' Complaint, Defendant Zimmer Holdings, Inc. ("ZHI"), subject to the pending Motion to Strike, denies each and every allegation, matter and thing alleged except as may be hereinafter admitted, qualified or explained, and states and alleges as follows (ZHI specifically reserves the right to amend this First Amended Answer subject to the Motion to Strike):

**PARTIES**

1. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of Plaintiffs' Complaint, and therefore denies same.
2. ZHI admits the allegations contained in paragraph 2 of Plaintiffs' Complaint.
3. ZHI admits the allegations contained in paragraph 3 of Plaintiffs' Complaint.

### **JURISDICTION**

4. ZHI admits that Zimmer, Inc. and Zimmer Holdings, Inc. are corporations incorporated under the laws of Delaware with headquarters in Warsaw, Indiana and that the matter in controversy exceeds \$75,000. The remainder of the allegations contained in paragraph 4 of Plaintiffs' Complaint state legal conclusions to which no response is required.

### **GENERAL BACKGROUND**

5. ZHI denies the allegations contained in paragraph 5 of Plaintiffs' Complaint.

6. ZHI admits that Zimmer, Inc. was purchased by Bristol-Myers Company in 1972. ZHI denies the remaining allegations contained in paragraph 6 of Plaintiffs' Complaint.

7. ZHI admits that Zimmer Holdings, Inc. was created in January 2001. ZHI denies the remaining allegations contained in paragraph 7 of Plaintiffs' Complaint.

8. On information and belief, ZHI admits that from time to time Zimmer, Inc. has sold products in the United States and in other countries. ZHI denies the remaining allegations contained in paragraph 8 of Plaintiffs' Complaint.

9. ZHI admits that from time to time Zimmer, Inc. has made public statements. ZHI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 9 of Plaintiffs' Complaint, and therefore denies same.

10. On information and belief, ZHI admits that Zimmer, Inc. sells products for use in the hip. On information and belief, ZHI denies the remaining allegations contained in paragraph 10 of Plaintiffs' Complaint.

11. On information and belief, ZHI denies the allegations contained in Paragraph 11 of Plaintiffs' Complaint.

12. On information and belief, ZHI admits there are different methods of fixation for a femoral component. On information and belief, ZHI denies the remaining allegations contained in Paragraph 12 of Plaintiffs' Complaint.

13. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 13 of Plaintiffs' Complaint, and therefore denies same.

14. On information and belief, ZHI denies the allegations contained in paragraph 14 of Plaintiffs' Complaint.

15. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 15 of Plaintiffs' Complaint, and therefore denies same.

16. On information and belief, ZHI admits that Zimmer, Inc. was assigned United States Patent 4,795,472. ZHI denies the remaining allegations contained in paragraph 16 of Plaintiffs' Complaint.

17. On information and belief, ZHI denies the allegations contained in paragraph 17 of Plaintiffs' Complaint.

18. On information and belief, ZHI denies the allegations contained in paragraph 18 of Plaintiffs' Complaint.

19. On information and belief, ZHI denies the allegations contained in paragraph 19 of Plaintiffs' Complaint.

20. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 20 of Plaintiffs' Complaint, and therefore denies same.

21. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 21 of Plaintiffs' Complaint, and therefore denies same.

22. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of Plaintiffs' Complaint, and therefore denies same.

23. On information and belief, ZHI denies the allegations contained in paragraph 23 of Plaintiffs' Complaint.

24. On information and belief, ZHI denies the allegations contained in paragraph 24 of Plaintiffs' Complaint.

**THE ZIMMER CENTRALIGN**

25. On information and belief, ZHI admits that Zimmer, Inc. introduced the Centralign in 1992. On information and belief, ZHI denies the remaining allegations contained in paragraph 25 of Plaintiffs' Complaint.

26. ZHI is without knowledge or information sufficient to form a belief as to whether Mr. Langford received a Centralign prosthesis, and therefore denies same. On information and belief, ZHI denies the remaining allegations contained in paragraph 26 of Plaintiffs' Complaint.

27. ZHI denies the allegations contained in paragraph 27 of Plaintiffs' Complaint.

28. On information and belief, ZHI denies the allegations contained in the first sentence of paragraph 28 of Plaintiffs' Complaint. ZHI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 28 of Plaintiffs' Complaint, and therefore denies same.

29. On information and belief, ZHI denies the allegations contained in paragraph 29 of Plaintiffs' Complaint.

30. On information and belief, ZHI denies the allegations contained in paragraph 30 of Plaintiffs' Complaint.

31. On information and belief, ZHI denies the allegations contained in paragraph 31 of Plaintiffs' Complaint.

32. On information and belief, ZHI denies the allegations contained in paragraph 32 of Plaintiffs' Complaint.

33. On information and belief, ZHI denies the allegations contained in paragraph 33 of Plaintiffs' Complaint.

34. On information and belief, ZHI denies the allegations contained in paragraph 34 of Plaintiffs' Complaint.

**PLAINTIFF'S INJURY**

35. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 35 of Plaintiffs' Complaint, and therefore denies same.

36. On information and belief, ZHI denies the allegations contained in paragraph 36 of Plaintiffs' Complaint.

37. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 37 of Plaintiffs' Complaint, and therefore denies same.

38. ZHI denies the allegations contained in paragraph 38 of Plaintiffs' Complaint.

**COUNT I  
Negligence**

39. ZHI incorporates its responses to paragraphs 1 through 38 of Plaintiffs' Complaint as if fully set forth herein.

40. The allegations contained in paragraph 40 of Plaintiffs' Complaint state a legal conclusion to which no response is required. To the extent a response is required, ZHI admits that when Zimmer, Inc. manufactures and sells products certain duties are imposed on Zimmer, Inc.

ZHI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 40 of Plaintiffs' Complaint, and therefore denies same.

41. ZHI denies the allegations contained in paragraph 41 of Plaintiffs' Complaint.

42. ZHI denies the allegations contained in paragraph 42 of Plaintiffs' Complaint, including subparagraphs a through g.

43. ZHI denies the allegations contained in paragraph 43 of Plaintiffs' Complaint.

44. ZHI denies the allegations contained in paragraph 44 of Plaintiffs' Complaint.

45. ZHI denies the allegations contained in paragraph 45 of Plaintiffs' Complaint.

**COUNT II**  
**Strict Product Liability (Failure to Warn)**

46. ZHI incorporates its responses to paragraphs 1 through 45 of Plaintiffs' Complaint as if fully set forth herein.

47. On information and belief, ZHI admits that Zimmer, Inc. manufactured and sold Centralign hip implants. On information and belief, ZHI denies the remaining allegations contained in paragraph 47 of Plaintiffs' Complaint.

48. ZHI denies the allegations contained in paragraph 48 of Plaintiffs' Complaint.

49. ZHI denies the allegations contained in paragraph 49 of Plaintiffs' Complaint.

50. ZHI denies the allegations contained in paragraph 50 of Plaintiffs' Complaint.

51. ZHI denies the allegations contained in paragraph 51 of Plaintiffs' Complaint.

**COUNT III**  
**Strict Product Liability (Defective Design, Manufacture and Testing)**

52. ZHI incorporates its responses to paragraphs 1 through 51 of Plaintiffs' Complaint as if fully set forth herein.

53. ZHI denies the allegations contained in paragraph 53 of Plaintiffs' Complaint, including subparagraphs a through h.

54. ZHI denies the allegations contained in paragraph 54 of Plaintiffs' Complaint.

**COUNT IV**  
**Breach of Express Warranties**

55. ZHI incorporates its responses to paragraphs 1 through 54 of Plaintiffs' Complaint as if fully set forth herein.

56. ZHI denies the allegations contained in paragraph 56 of Plaintiffs' Complaint.

57. ZHI denies the allegations contained in paragraph 57 of Plaintiffs' Complaint.

**COUNT V**  
**Breach of Implied Warranties**

58. ZHI incorporates its responses to paragraphs 1 through 57 of Plaintiffs' Complaint as if fully set forth herein.

59. ZHI denies the allegations contained in paragraph 59 of Plaintiffs' Complaint.

60. ZHI denies the allegations contained in paragraph 60 of Plaintiffs' Complaint.

**COUNT VI**  
**Deceptive Acts and Practices**

61. ZHI incorporates its responses to paragraphs 1 through 60 of Plaintiffs' Complaint as if fully set forth herein.

62. ZHI denies the allegations contained in paragraph 62 of Plaintiffs' Complaint.

63. ZHI denies the allegations contained in paragraph 63 of Plaintiffs' Complaint, including subparagraphs a through h.

64. ZHI denies the allegations contained in paragraph 64 of Plaintiffs' Complaint.

65. ZHI denies the allegations contained in paragraph 65 of Plaintiffs' Complaint.

**COUNT VII**  
**Loss of Consortium**

66. ZHI incorporates its responses to paragraphs 1 through 65 of Plaintiffs' Complaint as if fully set forth herein.

67. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 67 of Plaintiffs' Complaint, and therefore denies same.

68. ZHI denies the allegations contained in paragraph 68 of Plaintiffs' Complaint.

**AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

If Plaintiffs sustained injuries or incurred expenses as alleged, the same may have been caused in whole or in part by the conduct of one or more persons or entities for whose conduct ZHI was not responsible and with whom ZHI had no legal connection or no duty to control.

**SECOND AFFIRMATIVE DEFENSE**

If Plaintiffs sustained injuries or incurred expenses as alleged, the same were not due to, or caused by, the fault, lack of care, negligence, strict liability, or any other breach of duty on the part of ZHI.

**THIRD AFFIRMATIVE DEFENSE**

If Plaintiffs sustained injuries or incurred expenses as alleged, the same may have been the result of intervening and/or superseding causes, and not as a result of the acts or omissions of ZHI.

**FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs cannot recover under the Complaint because ZHI complied with all applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by



the United States, the State of Massachusetts, and/or by an agency of the United States or Massachusetts.

#### **FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by virtue of the intervention of a learned intermediary or intermediaries to whom any duty to warn was discharged.

#### **SIXTH AFFIRMATIVE DEFENSE**

ZHI's warnings and instructions were at all times in conformity with the generally recognized state of scientific and technological knowledge at the time such warnings and instructions were issued.

#### **SEVENTH AFFIRMATIVE DEFENSE**

At all times material to the Complaint, the product at issue was accompanied by reasonable instructions and warnings to the physician and other health-care providers.

#### **EIGHTH AFFIRMATIVE DEFENSE**

The products at issue were supplied, if at all, to a sophisticated user, and therefore, ZHI is not legally responsible for either the acts or omissions of the sophisticated user or misinformation or lack of information provided to the Plaintiff by others.

#### **NINTH AFFIRMATIVE DEFENSE**

Upon information and belief, if Plaintiffs sustained injuries or incurred expenses as alleged, the same may have been caused by misuse of the product, and such misuse could not have been reasonably expected.

**TENTH AFFIRMATIVE DEFENSE**

Upon information and belief, if Plaintiffs sustained injuries or incurred expenses as alleged, the same may have been caused by modification or alteration of the product, and such modification or alteration was not reasonably expected.

**ELEVENTH AFFIRMATIVE DEFENSE**

The product at issue is a prescription medical product that is neither defective nor unreasonably dangerous. At all times material to this incident, the product was reasonably safe and fit for its intended use and the warnings and instructions accompanying it at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate.

**TWELFTH AFFIRMATIVE DEFENSE**

The product at issue is neither defective nor unreasonably dangerous because it is a product which falls within the "comment k exception" to strict tort liability defined in Section 402A of the Restatement (Second) of Torts.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs are time-barred by virtue of the expiration of the applicable statute of limitations or applicable statute of repose, or the Equitable Doctrine of Laches.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' injuries, if any, were caused by pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses of the Plaintiff.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs have failed to state a claim upon which relief can be granted.

**SIXTEENTH AFFIRMATIVE DEFENSE**

In the event that Plaintiffs recover a verdict for personal injury, the amount of such recovery should be reduced by any payment that Plaintiffs received under the medical payment provisions, or any other provision, of any policy of insurance.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

In the event Plaintiffs recover a verdict for judgment against ZHI, then that verdict or judgment must be reduced by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiffs, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, worker's compensation or employee benefit program.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

That at all times mentioned in Plaintiffs' Complaint on file herein, the Plaintiffs assumed the risk; i.e. the Plaintiffs had actual knowledge and full appreciation of the probabilities and possibilities of risks attendant upon their actions and course of action, and voluntarily and without compulsion or coercion, encountered and assumed any and all such attendant risks.

**NINETEENTH AFFIRMATIVE DEFENSE**

The damages alleged by plaintiffs resulted from the negligent acts or omissions of the plaintiffs which negligence was greater than that of ZHI. Accordingly, the plaintiffs are barred from recovery from ZHI, in whole or in part, in accordance with M.G.L. c.231 sec. 85.

**TWENTIETH AFFIRMATIVE DEFENSE**

ZHI alleges that on balance, in light of the relevant factors, ZHI exercised the degree of care in its plan or design so as to avoid any unreasonable risk of harm to anyone who was likely to

be exposed to the dangers when the product was used in the manner for which the product was intended as well as an unintended yet reasonably foreseeable use.

#### **TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs failed to notify ZHI of the alleged deficiencies in the product within a reasonable time after the discovery of the alleged deficiencies.

#### **TWENTY-SECOND AFFIRMATIVE DEFENSE**

Any alleged warranty was disclaimed.

#### **TWENTY-THIRD AFFIRMATIVE DEFENSE**

The Complaint fails to state a cause of action against ZHI because the federal government has preempted the field of law applicable to the product alleged to have caused Plaintiffs' injuries. The granting of the relief prayed for in the Complaint would impede, impair, frustrate or burden the effectiveness of federal law regulating such field of law and would violate the Supremacy Clause (Art. VI, Clause 2) of the United States Constitution.

#### **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

ZHI expressly reserves the right to file further pleadings and to assert additional defenses as the proof develops.

#### **DEMAND FOR JURY TRIAL**

ZHI, pursuant to Rule 38 of the Federal Rules of Civil Procedure, respectfully demands a trial by jury on all issues so triable.

Respectfully submitted,

Dated: February 27, 2004

Zimmer Holdings, Inc.

By: 

Francis H. Morrison III (BBO # 645515)  
DAY, BERRY & HOWARD LLP  
CityPlace I  
Hartford, CT 06103-3499  
(860) 275-0100

Edgar B. Hatrick (BBO # 647166)  
DAY, BERRY & HOWARD LLP  
260 Franklin Street  
Boston, Massachusetts 02110  
(617) 345-4600

Matthew S. Elvin (pro hac vice)  
Dahm & Elvin LLP  
9604 Coldwater Road, Suite 201  
Fort Wayne, Indiana 46825  
Telephone: (260) 497-6000  
Facsimile: (260) 497-6019

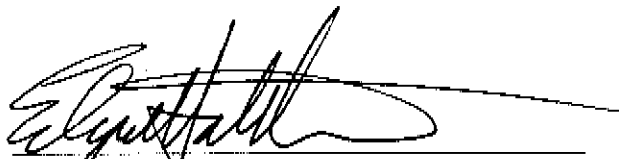
CERTIFICATE OF SERVICE

The undersigned certifies that on the 27th day of February, 2004, a copy of the foregoing ANSWER OF ZIMMER HOLDINGS, INC. was served on the following counsel of record by first-class mail, postage prepaid:

Wm. Gerald McElroy, Jr.  
Paul T. Sullivan  
Zelle, Hofmann, Voelbel, Mason & Gette LLP  
950 Winter Street, Suite 1300  
Waltham, Massachusetts 02451

Fred H. Pritzker  
Peter H. Berge  
Elliot L. Olsen  
Pritzker Ruohonen & Associates, P.A.  
Suite 4520  
33 South Sixth Street  
Minneapolis, Minnesota 55402-3792

James S. Reece  
Chad A. Snyder  
Elizabeth A. Maki  
Zelle, Hofmann, Voelbel, Mason & Gette LLP  
500 South Washington Avenue - Suite 4000  
Minneapolis, Minnesota 55415



Edgar B. Harrick